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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,391

10/15/2004

Andrea Parrino

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2102

22852 7590 02/01/2007

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EXAMINER

FRISTOE JR., JOHN K

ART UNIT

PAPER NUMBER

3753

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/511,391

Applicant(s)

PARRINO ET AL.

Examiner

John K. Fristoe Jr.

Art Unit

3753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 33-53 and 86-97 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11, 14-29, 31, 32, 54-61 and 63-85 is/are rejected.
- 7) ☒ Claim(s) 12, 13, 30 and 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-3, 5-97 have been considered but are moot in view of the new ground(s) of rejection. Since the new grounds of rejection were not necessitated by Applicant's amendment, the instant Office action remains non-final.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-25 and 65-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner how the grip can have a protrusion that passes through the fluid passage. In light of the above informalities, the claims have been examined as could best be understood by the examiner. The examiner's failure to apply prior art to any of the claims should not be construed as an indication of allowable subject matter.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5-11, 14, 15, 18-20, 26-29, 31, 32, 54-61, 63, 64 as well as 21-25, 65-69, 72-76, 78-82, 84, and 85 as far as they are definite, are rejected under 35 U.S.C. 102(b) as being

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anticipated by U.S. Pat. No. 5,569,235 (Ross et al.). Ross et al. disclose a connection element comprising a main body (12) made of a rigid material, at least one fluid passage (within element 48 in figure 3A), a first opening (within element 18), a second opening (66), wherein the first opening (within element 18) is at a distance from the second opening (66), a first tube (attaches to element 22), a shut off element (24) made of an elastically deformable material (col. 3, line 25), a fixing portion (30), an intermediate portion (26) that is deformable (Figure 3B), a sealing portion (28), a first operating condition (figure 3A), a second operating condition (figure 3B), a second distance (seen in figure 3B), an outer surface (surface of element 24), a transverse end surface (surface of element 30) that is swept by fluid (fluid flow seen by arrows in figure 3B), a lateral surface (outside surface of element 26) that is swept by fluids (fluid flow seen by arrows in figure 3B), wherein the intermediate portion (26) deforms symmetrically (seen in figure 3B), a leading edge (surface of element 18 in figure 3A), wherein the sealing portion (28) cooperates with the leading edge (surface of element 18 in figure 3A) so that the distal surface has a continuous or level distal surface (surface where element 28 cooperates with element 18 in figure 3A), wherein the lateral surface constitutes a surface of revolution (element 26 in figure 2), a fluid channel (within element 12 seen in figure 3B) that is axially symmetric both in the first operating condition (Figure 3A) and the second operating condition (figure 3B), an outer body (14), a core (16) that extends coaxial with the shut off element (24), an attachment portion (60), a tubular expansion (22), a distal portion (within element 18 in figure 3A), a proximal portion (within element 22 in figure 3A), a joining portion (adjacent element 50 in figure 3A), wherein the intermediate portion (26) deforms at a substantially constant dimension (figure 3B), means (68) for connecting a second tube, a first annular sealing element (29), wherein the tubular

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expansion (22) engages the terminal portion of the first tube (attaches to element 22), wherein the sealing portion (28), the intermediate portion (26), and the fixing portion (30) are made of a single piece of elastomeric material (col. 3, line 25), a grip (surface of element 14 in figure 1), a protrusion (lip adjacent element 12 in figure 1), a recess (cut out rim of element 16 in figure 1), a second tube (70), an auxiliary connection (78), an auxiliary main body (72), an auxiliary fluid passage (within element 76), and a male member (76) that is axially symmetric (figure 5).

Regarding the tubs connecting to the distal and proximal end of the connector and the tubes being a part of peritoneal dialysis line, the examiner takes official notice that luer fittings at each end of the connector are capable of being connected to any medical instrument including a tube.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16 as well as 70 as far as it is definite are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,569,235 (Ross et al.) in view of U.S. Pat. No. 4,745,950 (Mathieu). Ross et al. disclose a connection element comprising a main body (12) made of a rigid material, at least one fluid passage (within element 48 in figure 3A), a first opening (within element 18), a second opening (66), wherein the first opening (within element 18) is at a distance from the second opening (66), a first tube (attaches to element 22), a shut off element (24) made of an elastically deformable material (col. 3, line 25), a fixing portion (30), an intermediate portion (26) that is deformable (Figure 3B), a sealing portion (28), a first operating condition

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(figure 3A), a second operating condition (figure 3B), a second distance (seen in figure 3B), an outer surface (surface of element 24), a transverse end surface (surface of element 30) that is swept by fluid (fluid flow seen by arrows in figure 3B), a lateral surface (outside surface of element 26) that is swept by fluids (fluid flow seen by arrows in figure 3B), wherein the intermediate portion (26) deforms symmetrically (seen in figure 3B), a leading edge (surface of element 18 in figure 3A), wherein the sealing portion (28) cooperates with the leading edge (surface of element 18 in figure 3A) so that the distal surface has a continuous or level distal surface (surface where element 28 cooperates with element 18 in figure 3A), wherein the lateral surface constitutes a surface of revolution (element 26 in figure 2), a fluid channel (within element 12 seen in figure 3B) that is axially symmetric both in the first operating condition (Figure 3A) and the second operating condition (figure 3B), an outer body (14), a core (16) that extends coaxial with the shut off element (24), an attachment portion (60), a tubular expansion (22), a distal portion (within element 18 in figure 3A), a proximal portion (within element 22 in figure 3A), a joining portion (adjacent element 50 in figure 3A), wherein the intermediate portion (26) deforms at a substantially constant dimension (figure 3B), means (68) for connecting a second tube, a first annular sealing element (29), wherein the tubular expansion (22) engages the terminal portion of the first tube (attaches to element 22), wherein the sealing portion (28), the intermediate portion (26), and the fixing portion (30) are made of a single piece of elastomeric material (col. 3, line 25), a grip (surface of element 14 in figure 1), a protrusion (lip adjacent element 12 in figure 1), a recess (cut out rim of element 16 in figure 1), a second tube (70), an auxiliary connection (78), an auxiliary main body (72), an auxiliary fluid passage (within element 76), and a male member (76) that is axially symmetric (figure 5) but lacks an annular

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sealing element on the outside of the main body at the distal end and a second annular seal spaced a distance from the distal end. Mathieu teaches a connector element comprising a main body (12) and a sealing element (66) on the outside of the main body (12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connection element of Ross et al. by adding a sealing element to the outside of the main body as taught by Mathieu in order to seal the connection between the tube and the connector more effectively.

8. Claims 17 as well as 71 as far as it is definite are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,569,235 (Ross et al.) in view of U.S. Pat. No. 4,745,950 (Mathieu) and U.S. Pat. No. 4,638,668 (Leverberg et al.). Ross et al. disclose a connection element comprising a main body (12) made of a rigid material, at least one fluid passage (within element 48 in figure 3A), a first opening (within element 18), a second opening (66), wherein the first opening (within element 18) is at a distance from the second opening (66), a first tube (attaches to element 22), a shut off element (24) made of an elastically deformable material (col. 3, line 25), a fixing portion (30), an intermediate portion (26) that is deformable (Figure 3B), a sealing portion (28), a first operating condition (figure 3A), a second operating condition (figure 3B), a second distance (seen in figure 3B), an outer surface (surface of element 24), a transverse end surface (surface of element 30) that is swept by fluid (fluid flow seen by arrows in figure 3B), a lateral surface (outside surface of element 26) that is swept by fluids (fluid flow seen by arrows in figure 3B), wherein the intermediate portion (26) deforms symmetrically (seen in figure 3B), a leading edge (surface of element 18 in figure 3A), wherein the sealing portion (28) cooperates with the leading edge (surface of element 18 in figure 3A) so that the distal surface

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has a continuous or level distal surface (surface where element 28 cooperates with element 18 in figure 3A), wherein the lateral surface constitutes a surface of revolution (element 26 in figure 2), a fluid channel (within element 12 seen in figure 3B) that is axially symmetric both in the first operating condition (Figure 3A) and the second operating condition (figure 3B), an outer body (14), a core (16) that extends coaxial with the shut off element (24), an attachment portion (60), a tubular expansion (22), a distal portion (within element 18 in figure 3A), a proximal portion (within element 22 in figure 3A), a joining portion (adjacent element 50 in figure 3A), wherein the intermediate portion (26) deforms at a substantially constant dimension (figure 3B), means (68) for connecting a second tube, a first annular sealing element (29), wherein the tubular expansion (22) engages the terminal portion of the first tube (attaches to element 22), wherein the sealing portion (28), the intermediate portion (26), and the fixing portion (30) are made of a single piece of elastomeric material (col. 3, line 25), a grip (surface of element 14 in figure 1), a protrusion (lip adjacent element 12 in figure 1), a recess (cut out rim of element 16 in figure 1), a second tube (70), an auxiliary connection (78), an auxiliary main body (72), an auxiliary fluid passage (within element 76), and a male member (76) that is axially symmetric (figure 5) but lacks an annular sealing element on the outside of the main body at the distal end and a second annular seal spaced a distance from the distal end. Mathieu teaches a connector element comprising a main body (12) and an annular sealing element (66) on the outside of the main body (12). Leverberg et al. teach a connector comprising a main body (2) and an annular sealing element (24) at a distance from the distal end (near element 29 in figure 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connection element of Ross et al. by incorporating an annular seal at the distal end as taught by



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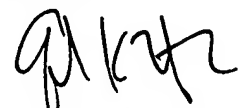
Mathieu and an annular seal spaced from the distal end as taught by Leverberg et al. in order to seal the connection between the tube and the connector more effectively.

*Allowable Subject Matter*

9. Claims 33-53 and 86-97 are allowed.
10. Claims 12, 13, 30, and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (571) 272-4926. The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric S. Keasel can be reached on (571) 272-4929. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John K. Fristoe Jr.  
Examiner  
Art Unit 3753

JKF